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Sub	Substitute for form 1449/PTO			Complete if Known		
				Application Number	10/580,746-Conf. #9342	
١N	<b>VEORMATION</b>	I DI	SCLOSURE	Filing Date	May 26, 2006	
STATEMENT BY APPLICANT				First Named Inventor	Ingmar Hoerr	
				Art Unit	1636	
	(Use as many sh	eets as	necessary)	Examiner Name	M. Marvich	
Sheet	1	of	11	Attorney Docket Number	22122-00006-US1	

			U.S. PA	TENT DOCUMENTS	
Examiner Initials*	Cite No.1	Document Number  Number-Kind Code <sup>2</sup> ( <i>if known</i> )	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA*	US-3,906,092	09-16-1975	Hilleman et al.	
	AB*	US-4,373,071	02-08-1983	Itakura	
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	ВА	WO-93/14778-A1	08-05-1993	Vical Inc		
	ВВ	WO-97/41210-A1	11-06-1997	Univ Duke et al.		
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	BE	EP-1 083 232-A1	03-14-2001	Jung Guenther Prof Dr et al.		
	BF	WO-00/29561-A2	05-25-2000	Statens Seruminstitut et al.		

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Signature		Considered	

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Sub	Substitute for form 1449/PTO			Complete if Known		
				Application Number	10/580,746-Conf. #9342	
١N	<b>IFORMATION</b>	N DI	SCLOSURE	Filing Date	May 26, 2006	
STATEMENT BY APPLICANT			APPLICANT	First Named Inventor	Ingmar Hoerr	
				Art Unit	1636	
	(Use as many sh	eets as	s necessary)	Examiner Name	M. Marvich	
Sheet	2	of	11	Attorney Docket Number	22122-00006-US1	

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	AT*	US-6,322,967-B1	11-27-2001	Parkin		
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	AV*	US-20020132788-A1	09-19-2002	Lewis et al.		
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	AX*	US-6,514,948-B1	02-04-2003	Raz et al.		
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	AZ*	US-6,589,940-B1	07-08-2003	Raz et al.		
	AA1*	US-20030143204-A1	07-31-2003	Lewis et al.		
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	AE1*	US-6,664,066-B2	12-16-2003	Parks		
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	Al1*	US-20050032730-A1	02-10-2005	Von Der Mulbe et al.		
	AJ1*	US-20050037494-A1	02-17-2005	Hecker et al.		
	AK1*	US-20050059624-A1	03-17-2005	Hoerr et al.	See BH	
	AL1*	US-20050064596-A1	03-24-2005	Riemen et al.		

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	BG	WO-03/028656-A2	04-10-2003	Chiron Corp et al.		
	ВН	WO-03/051401-A2	06-26-2003	Curevac Gmbh et al.	See AK1	
	BI	WO-03/059381-A2	07-24-2003	Curevac Gmbh et al.		
	BJ	WO-03/066649-A1	08-14-2003	Biomira Inc et al.		
	BK	EP-1 393 745-A1	03-03-2004	Hybridon Inc		
	BL	WO-2004/058159-A2	07-15-2004	Dynavax Tech Corp et al.		

Examiner	Date	
Signature	Considered	

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IN.	<b>NFORMATION</b>	I DI	SCLOSURE	Filing Date	May 26, 2006	
S	STATEMENT BY APPLICANT			First Named Inventor	Ingmar Hoerr	
				Art Unit	1636	
	(Use as many sh	eets as	necessary)	Examiner Name	M. Marvich	
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	AM1*	US-7,001,890-B1	02-21-2006	Wagner et al.	
	AN1*	US-20060172966-A1	08-03-2006	Lipford et al.	
	AO1*	US-2006/0188490- A1	08-24-2006	Hoerr et al.	
	AP1*	US-20060241076-A1	10-26-2006	Uhlmann et al.	
	AQ1*	US-7,208,478-B2	04-24-2007	Carson et al.	
	AR1*	US-7,276,489-B1	10-02-2007	Agrawal et al.	
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	ВМ	WO-2007/024708-A2	03-01-2007	Univ Pennsylvania et al.					

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Sub	ostitute for form 1449/PTO			Complete if Known		
				Application Number	10/580,746-Conf. #9342	
l IN	VFORMATION	I DI	SCLOSURE	Filing Date	May 26, 2006	
S	TATEMENT B	3Y A	APPLICANT	First Named Inventor	Ingmar Hoerr	
				Art Unit	1636	
	(Use as many sh	eets as	necessary)	Examiner Name	M. Marvich	
Sheet	Sheet 4 of 11			Attorney Docket Number	22122-00006-US1	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	CA	O'DOHERTY, U., et al., Human blood contains two subsets of dendritic cells, one immunologically mature and the other immature. <i>Immunology</i> <b>82</b> (1994), 487-493.	
	СВ	TEUFEL, R., et al., Human peripheral blood mononuclear cells transfected with messenger RNA stimulate antigen-specific cytotoxic T-lymphocytes in vitro. <i>Cell. Mol. Life Sci.</i> <b>62</b> (2005), 1755-1762.	
	СС	ROMANI, N., et al., Generation of mature dendritic cells from human blood - An improved method with special regard to clinical applicability. <i>Journal of Immunological Methods</i> <b>196</b> (1996, 137-151.	
	CD	MORSE, M., et al., Generation of dendritic cells <i>in vitro</i> from peripheral blood mononuclear cells with granulocytemacrophage-colony-stimulating factor, interleukin-4, and tumor necrosis factor-α for use in cancer immunotherapy. <i>Annals of Surgery</i> <b>226(1)</b> (1997), 6-16.	
	CE	FEARNLEY, D.B., et al., Monitoring Human Blood Dendritic Cell Numbers in Normal Individuals and in Stem Cell Transplantation. <i>Blood</i> <b>93(2)</b> (1999, 728-736.	
	CF	SIENA, S., et al., Expansion of Immunostimulatory Dendritic Cells from Peripheral Blood of Patients with Cancer. <i>The Oncologist</i> <b>2</b> (1997), 65-69.	
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	CI	HEISER, A., et al., Autologous dendritic cells transfected with prostate-specific antigen RNA stimulate CTL responses against metastatic prostate tumors. <i>The Journal of Clinical Investigation</i> <b>109(3)</b> (2002), 409-417.	
	CJ	HEISER, A., et al., Human Dendritic Cells Transfected with RNA Encoding Prostate-Specific Antigen Stimulate Prostate-Specific CTL Responses in Vitro. <i>The Journal of Immunology</i> (2000), 5508-5514.	

Examiner	Date	
Signature	Considered	

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	ск	HOLMES, D., et al., Cell Positioning and Sorting using Dielectrophoresis. European Cells and Materials 4(Suppl. 2) (2002), 120-122.	
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	СР	CONRY, R.M. et al., Characterization of a messenger RNA Polynucleotide Vaccine Vector. Cancer Research <b>55</b> (1995), 1397-1400.	
	CQ	HOERR, I., <i>In vivo</i> application of RNA leads to induction of specific cytotoxic T lymphocytes and antibodies. <i>Eur. J. Immunol.</i> <b>30</b> (2000), 1-7.	
	CR	BOCZKOWSKI, D., et al., Induction of Tumor Immunity and Cytotoxic T Lymphocyte Responses Using Dendritic Cells Transfected with Messenger RNA Amplified from Tumor Cells. Cancer Research 60 (2000), 1028-1034.	
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	СТ	WU, L. et al., Fusion protein vectors to increase protein production and evaluate the immunogenicity of genetic vaccines. <i>Mol. Ther.</i> <b>2(3)</b> (2000), 288-297. (ABSTRACT ONLY)	

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Signature	Considered	

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				Art Unit	1636	
	(Use as many sh	eets as	necessary)	Examiner Name	M. Marvich	
Sheet	Sheet 6 of 11			Attorney Docket Number	22122-00006-US1	

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	CB1	DUNHAM, S.P., The application of nucleic acid vaccines in veterinary medicine. Research in Veterinary Science <b>73</b> (2002), 9-16.	
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	CD1	LUO, D. et al., Synthetic DNA delivery system. Nature Biotechnology 18 (2000), 33-37.	

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10580746 - GAU: 1633 Receipt date: 02/09/2010

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•	CE1	VERMA, I.M. et al., Gene therapy - promises, problems and prospects. Nature 389, 239-242.	
	CF1	EDELSTEIN, M.L. et al., Gene therapy clinical trials worldwide 1989-2004 - an overview. <i>J. Gene Med.</i> <b>6</b> (2004), 597-602.	
	CG1	PALU, G. et al., In pursuit of new developments for gene therapy of human diseases. <i>Journal of Biotechnology</i> <b>68</b> (1999), 1-13.	
	CH1	KUDIA, G. et al., High Guanine and Cytosine Content Increases mRNA Levels in Mammalian Cells. <i>PLoS Biol</i> <b>4(6)</b> (2006): e180. DOI: 10.1371/journal.pbio.0040180.	
	CI1	WILUSZ, C.J. et al., Bringing the role of mRNA decay in the control of gene expression into focus. <i>TRENDS in Genetics</i> <b>20(10)</b> (2004), 491-497.	
	CJ1	TOURRIERE, H. et al., mRNA degradation machines in eukaryotic cells. <i>Biochimie</i> <b>84</b> (2002), 821-837.	
	CK1	MITCHELL, P. et al., mRNA turnover. Current Opinion in Cell Biology 13 (2001), 320-325.	
	CL1	ROITT, BROSTOFF AND MALE. Immunology, 4th Edition. Barcelona: Times Mirror International Publishers Limited, 1996, page 1.7.	
	СМ1	ROSS, J., Control of messenger RNA stability in higher eukaryotes. <i>Trends Genet.</i> <b>12(5)</b> :171-5, May 1996.	
	CN1	UEDA, T. et al., Phosphorothioate-containing RNAs show mRNA activity in the prokaryotic translation systems <i>in vitro</i> . <i>Nucleic Acids Research</i> <b>19(3)</b> (1991), 547-552.	

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Substitute for form 1449/PTO				Complete if Known		
				Application Number	10/580,746-Conf. #9342	
l IN	<b>VEORMATION</b>	1 DI	SCLOSURE	Filing Date	May 26, 2006	
S	STATEMENT BY APPLICANT		APPLICANT	First Named Inventor	Ingmar Hoerr	
				Art Unit	1636	
	(Use as many sh	eets as	necessary)	Examiner Name	M. Marvich	
Sheet	8	of	11	Attorney Docket Number	22122-00006-US1	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	CO1	TRINCHIERI, G. et al., Cooperation of Toll-like receptor signals in innate immune defence. <i>Nature Reviews/Immunology</i> <b>7</b> (2007), 179-190.	
	CP1	RAMAZEILLES, C. et al., Antisense phosphorothioate oligonucleotides: Selective killing of the intracellular parasite <i>Leishmania amazonensis</i> . <i>Proc. Natl. Acad. Sci. USA</i> <b>91</b> (1994), 7859-7863.	
	CQ1	DIEBOLD, S.S. et al., Innate Antiviral Responses by Means of TLR7-Mediated Recognition of Single-Stranded RNA. <i>Science</i> <b>303</b> (2004), 1529-1531.	
C	CR1	HEMMI, H. et al., A Toll-like receptor recognizes bacterial DNA. Nature 408 (2000), 740-745.	
	CS1	ZHOU, WZ. et al., RNA Melanoma Vaccine: Induction of Antitumor Immunity by Human Glycoprotein 100 mRNA Immunization. <i>Human Gene Therapy</i> <b>10</b> (1999), 2719-2724.	
	CT1	MATRAY, T.J. et al., Synthesis and properties of RNA analogs - oligoribonucleotide N3'→P5' phosphoramidates. <i>Nucleic Acids Research</i> <b>27(20)</b> (1999), 3976-3985.	
	CU1	NICHOLSON, A. et al., Accurate <i>in vitro</i> cleavage by RNase III of phosphorothioate- substituted RNA processing signals in bacteriophage T7 early mRNA. <i>Nucleic Acids</i> <i>Research</i> <b>16(4)</b> (1988), 1577-1591.	
	CV1	MINKS, M.A. et al., Structural Requirements of Double-stranded RNA for the Activation of 2',5'-Oligo(a) Polymerase and Protein Kinase of Interferon-treated HeLa Cells. <i>The Journal of Biological Chemistry</i> <b>254(20)</b> (1979), 10180-10183.	
	CW1	JANSSENS, S. et al., Role of Toll-Like Receptors in Pathogen Recognition. <i>Clinical Microbiology Reviews</i> <b>16(4)</b> (2003), 637-646.	
	CX1	GRANSTEIN, R.D. et al., Induction of Anti-Tumor Immunity with Epidermal Cells Pulsed with Tumor-Derived RNA or Intradermal Administration of RNA. <i>J. Invest. Dermatol.</i> <b>114</b> (2000), 632-636.	

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	CY1	SAENZ-BADILLOS, J. et al., RNA as a tumor vaccine: a review of the literature. <i>Exp. Dermatol.</i> <b>10</b> (2001), 143-154.	
	CZ1	LOGING, W.T. et al., Identifying Potential Tumor Markers and Antigens by Database Mining and Rapid Expression Screening. <i>Genome Research</i> 10 (2000), 1393-1402.	
	CA2	WEIDE, B. et al., Results of the first phase I/II clinical vaccination trail with direct injection of mRNA. <i>J. Immunother.</i> <b>31(2)</b> (2008), 180-188. (Abstract only)	
	CB2	SU, Z. et al., Immunological and Clinical Responses in Metastatic Renal Cancer Patients Vaccinated with Tumor RNA-transfected Dendritic Cells. <i>Cancer Research</i> <b>63</b> (2003), 2127-2133.	
	CC2	WEIDE, B. et al., Results of the First Phase 1/2 of Clinical Vaccination Trial with Direct Injection of mRNA. <i>J. Immunother.</i> <b>00(00)</b> , 1-9. <b>2007</b>	
	CD2	CARRALOT, J-P. et al., Production and characterization of amplified tumor-derived cRNA libraries to be used as vaccines against metastatic melanomas. <i>Genetic Vaccines and Therapy</i> <b>3</b> (2005), 6.	
	CE2	LENZ, A. et al., Human and Murine Dermis Contain Dendritic Cells. <i>J. Clin. Invest.</i> <b>92</b> (1993), 2587-2596.	
	CF2	ROSENBERG, S.A. et al., Cancer immunotherapy: moving beyond current vaccines. <i>Nat Mec.</i> <b>10(9)</b> (2004), 909-915.	
	CG2	HOATH, S.B. et al., The Organization of Human Epidermis: Functional Epidermal Units and Phi Proportionality. <i>J. Invest. Dermatol.</i> <b>121</b> (2003), 1440-1446.	
	CH2	MEUNIER, L. et al., Heterogeneous Populations of Class II MHC+ Cells in Human Dermal Cell Suspensions. <i>The Journal of Immunology</i> <b>151(8)</b> (1993), 4067-4080.	

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	(Use as many sh	eets as	necessary)	Examiner Name	M. Marvich	
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	Cl2	MATHERS, A.R. et al., Professional Antigen-Presenting Cells of the Skin. <i>Immunologic Research</i> <b>36/1-3</b> (2006), 127-136.	
	CJ2	PALUCKA, A.K. et al., Taming cancer by inducing immunity via dendritic cells. <i>Immunological Reviews</i> <b>220</b> (2007), 129-150.	
	СК2	LARREGINA, A.T. et al., Changing Paradigms in Cutaneous Immunology: Adapting with Dendritic Cells. <i>The Journal of Investigative Dermatology</i> <b>124</b> (2005), 1-12.	
	CL2	KARIKO, K. et al., Suppression of RNA Recognition by Toll-like Receptors: The Impact of Nucleoside Modification and the Evolutionary Origin of RNA. <i>Immunity</i> <b>23</b> (2005), 165-175.	
	CM2	KANDIMALLA, E.R. et al., Divergent synthetic nucleotide motif recognition pattern: design and development of potent immunomodulatory oligodeoxyribonucleotide agents with distinct cytokine induction profiles. <i>Nucleic Acids Research</i> <b>31(9)</b> (2003), 2393-2400.	
	CN2	KANDIMALLA, E.R. et al., Immunomodulatory oligonucleotides containing a cytosine-phosphate-2'-deoxy-7-deazaguanosine motif as potent Toll-like receptor 9 agonists. <i>PNAS</i> <b>102(19)</b> (2005), 6925-6930.	
	CO2	LEE, J. et al., Molecular basis for the immunostimulatory activity of guanine nucleoside analogs: Activation of Toll-like receptor 7. <i>PNAS</i> <b>100(11)</b> (2003), 6646-6651.	
	CP2	AURUP, H. et al., Translation of 2'-modified mRNA in vitro and in vivo. Nucleic Acids Research 22(23) (1994), 4963-4968.	
	CQ2	DISBROW, G.L., Codon optimization of the HPV-16 E5 gene enhances protein expression. <i>Virology</i> <b>311</b> (2003), 105-114.	
	CR2	SOUSA, R., Use of T7 RNA Polymerase and Its Mutants for Incorporation of Nucleoside Analogs into RNA. <i>Methods in Enzymology</i> <b>317</b> (2000), 65-74.	

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	CS2	GAO, X. et al., "Nonviral gene delivery: what we know and what is next." AAPS J 9(1): E92-E104 (2007).	
	CT2	HERWEIJER, H. et al., "Gene therapy progress and prospects: Hydrodynamic gene delivery." <i>Gene Ther.</i> <b>14</b> (2): 99-107 (2007).	
	CU2	SUDA, T. et al., "Hydrodynamic gene delivery: its principles and applications." <i>Mol. Ther.</i> <b>15</b> (12): 2063-2069 (2007).	
	CV2	VERMA, I.M. et al., "Gene therapy: twenty-first century medicine." <i>Annu. Rev. Biochem.</i> <b>74</b> : 711-738 (2005).	
	CW2	WOLFF, J.A. et al., "Direct gene transfer into mouse muscle in vivo." Science <b>247</b> (4949 Pt. 1): 1465-1468 (1990).	

Examiner Signature	/Maria Marvich/	Date Considered	05/08/2010

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